UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

FEDERAL TRADE COMMISSION and THE PEOPLE OF THE STATE OF NEW YORK, by LETITIA JAMES, Attorney General of the State of New York, Plaintiffs, v. QUINCY BIOSCIENCE HOLDING COMPANY, INC., a corporation; QUINCY BIOSCIENCE, LLC, a limited liability company; PREVAGEN, INC., a corporation d/b/a SUGAR RIVER SUPPLEMENTS; QUINCY BIOSCIENCE MANUFACTURING LLC, a limited liability company; and MARK UNDERWOOD, individual and as an officer of QUINCY BIOSCIENCE HOLDING COMPANY, INC., QUINCY BIOSCIENCE, LLC, and PREVAGEN, INC. Defendants.	Case No. 1:17-cv-00124-LLS

DECLARATION OF MARK UNDERWOOD

I, Mark Underwood, pursuant to 28 U.S.C. § 1746, declare as follows:

1. I am the President and co-founder of Quincy Bioscience Holding Company, Inc., Quincy Bioscience, LLC, Prevagen, Inc., and Quincy Bioscience Manufacturing LLC (collectively "Quincy").

2. I make this declaration based on my personal knowledge, and where indicated, based on my review of Quincy's records kept and maintained in the ordinary course of business. If called as a witness, I could and would competently testify to the matters stated herein.

3. I make this declaration in support of Defendants' motion for summary judgment in the above-captioned action.

Prevagen

4. Prevagen® is a dietary supplement marketed and sold by Prevagen, Inc.

5. Apoaequorin, one of the active ingredients in Prevagen, is a calcium-binding protein derived from aequorin, which was originally discovered in the aequorea victoria jellyfish.

6. Prevagen was first made available for sale in the United States in 2007.

7. The Prevagen line of products include three different dosages (Regular Strength, Extra Strength, and Professional), two different formats (capsules and chewable tablets), two different sizes (30 and 60 count) and multiple different types of packages.

8. In or around 2016, the Prevagen line of products were reformulated to include 50 micrograms of vitamin D3 (in addition to apoaequorin) per capsule or chewable tablet, which is equivalent to 2000 IU of vitamin D.

9. Prevagen's target market is, and always has been, healthy, older, community-dwelling adults who are cognitively normal or who have mild cognitive impairment due to the normal aging process.

10. Quincy reviewed, consulted and relied upon the Federal Trade Commission's "Dietary Supplements: An Advertising Guide for Industry" (the "FTC Guidance") when considering and creating marketing and advertising claims for Prevagen.

11. Quincy has engaged outside counsel to review the available scientific evidence relating to apoaequorin and vitamin D and cognitive function to confirm that the labels and advertisements for Prevagen comply with all applicable laws and regulations, including the FTC Guidance.

12. Quincy's outside counsel has also been involved with the creation, editing, review, clearance, approval, placement and/or dissemination of labels and advertisements for Prevagen.

Animal Studies

13. In or about November 2004, Quincy entered into a research agreement with the Neurophysiology and Behavior Laboratory, University of Wisconsin-Milwaukee (the "Lab"). The Lab started conducting, and continues to conduct, numerous studies on apoaequorin in animal models.

14. The animal studies conducted by the Lab consistently reported that apoaequorin provides a cognitive benefit, including neuroprotective effects.

15. True and correct copies of results of animal studies conducted by the Lab were produced in discovery and are attached hereto as follows:

Exhibit A	*Aequorin Protects Adult and Aging Hippocampal CA1 Neurons From Ischemic Cell Death*	QUI-FTCNY-00149905
Exhibit B	*Orally administered apoaequorin protects neurons from oxygen-glucose deprivation*	QUI-FTCNY-00149910
Exhibit C	*Use of an Acute Brain Slice Model of Ischemia to Study the Direct Application of Neurotherapeutics*	QUI-FTCNY-00149906; QUI-FTCNY-00150086
Exhibit D	*Apoaequorin protects neurons from ischemia and alters cytokine mRNA levels in rat hippocampus*	QUI-FTCNY-00149908
Exhibit E	*The Neurotherapeutic Effects of the Calcium Binding Protein Apoaequorin*	QUI-FTCNY-00150018

Exhibit F	*Effect of intrahippocampal infusion of Apoaequorin on cytokine protein expression.*	QUI-FTCNY- 00150019
Exhibit G	*Neuroprotective Effects of Aequorin on Hippocampal CA1 Neurons Following Ischemia*	QUI-FTCNY-00150121; QUI-FTCNY-00150079
Exhibit H	*Aequorin Protects Adult and Aging Hippocampal CA1 Neurons From Ischemic Cell Death*	QUI-FTCNY-00150122; QUI-FTCNY-00150080
Exhibit I	*Neuroprotection of Hippocampal CA1 Neurons from Ischemic Cell Death Using the Calcium Binding Protein Aequorin*	QUI-FTCNY-00150124; QUI-FTCNY-00150082
Exhibit J	*Time Course and Effectiveness of Apoaequorin as a Neuroprotectant in the Brain*	QUI-FTCNY-00150125
Exhibit K	*Oral administration of AQ is neuroprotective in an acute slice model*	QUI-FTCNY-00150127
Exhibit L	*The Calcium Binding Protein Apoaequorin Alters Cytokine Expression Following Direct Hippocampal Brain Infusion In A Rat Model*	QUI-FTCNY-00150128

16. Certain results of animal studies performed at the Lab that reported apoaequorin's neuroprotective effects were published in a peer-reviewed journal. A true and correct copy of Detert JA, et al., Pretreatment with apoaequorin protects hippocampal CA1 neurons from oxygen-glucose deprivation, PLos One, 2013; 8(11):e790002 was produced in discovery as QUI-FTCNY-00149866—001489875) and is attached hereto as Exhibit M.

17. In addition to the studies performed by the Lab, Quincy has also sponsored research on apoaequorin through canine models.

18. Research on apoaequorin in canine models reported evidence that apoaequorin provides beneficial cognitive effects. True and correct copies of the results of these canine studies

are attached hereto as Exhibit N (QUI-FTCNY-00150040) and Exhibit O (QUI-FTCNY-00150179—00150184).

19. Results of the canine studies reporting apoaequorin's beneficial cognitive effects in canines were published in a peer-reviewed journal. *See* Exhibit O; Journal of Veterinary Behavior, Milgram, et al., *A Novel Mechanism for Cognitive Enhancement in Aged Dogs with the Use of a Calcium-Buffering Protein*.

Human Clinical Studies

20. Between approximately May 2008 and January 2009, Quincy conducted an open label human clinical trial (the "Open Label Trial") consisting of approximately 55 adult participants to assess the impact of apoaequorin on general health and quality of life. A true and correct copy of a write-up of the Open Label Trial was produced in discovery as QUI-FTCNY-00149861—00149865 and is attached hereto as Exhibit P.

21. Between 2009 and 2011, Quincy conducted the Madison Memory Study, a 90-day randomized, double-blind, placebo-controlled study designed "to determine whether Prevagen with apoaequorin (10 mg) improves quantitative measures of cognitive function in community dwelling, older adults." A true and correct copy of Kenneth C. Lerner, *Madison Memory Study: A Randomized, Double-Blinded, Placebo-Controlled Trial of Apoaequorin in Community-Dwelling, Older Adults* (Aug. 1, 2016), was produced in discovery as QUI-FTCNY-00003696—00003705 and is attached hereto as Exhibit Q.

22. For the Madison Memory Study, 218 adults aged 40 to 91, each with self-reported memory difficulties, were randomly assigned to receive either apoaequorin capsules or placebos, and were instructed to take one capsule per day. (*See* Ex. Q at 4.)

23. Examiners obtained a baseline cognitive score for each participant using an eight-question screening tool called "AD8," used to differentiate between adults facing normal cognitive aging and those with early signs of dementia. (*See* Ex. Q at 2.)

24. AD8 scores of 0 to 2 are considered reflective of normal aging or "very mild" cognitive impairment. (*See* Ex. Q at 2.)

25. Accordingly, participants with AD8 scores of 0 to 2 were the target population for the Madison Memory Study. While Quincy did not exclude any participants based on AD8 score, the Madison Memory Study used an AD8 score of 2 as a cut-off value to discriminate between those people who are cognitively normal or who have mild or very mild cognitive impairment (AD8 0-2) versus those with higher levels of impairment (AD8 3-8). (*See* Ex. Q at 2.)

26. The protocol for the Madison Memory listed a planned sample size of 100 participants. A true and correct coy of the protocol for the Madison Memory Study was produced in discovery at QUI-FTCNY-00068424—00068429 and is attached hereto as Exhibit R.

27. The Madison Memory Study included 100 participants who reported an AD8 score of 0-2. (*See* Ex. Q at 5.)

28. Quincy decided to analyze certain groups of participants based on AD8 scores before the Madison Memory Study commenced.

29. The recruitment materials from the Madison Memory Study were targeted towards healthy, older adults (i.e. those with AD8 scores between 0 and 2). A true and correct copy of a recruitment poster for the Madison Memory Study produced in discovery as QUI-FTCNY-00068566 is attached hereto as Exhibit S.

30. The data from the Madison Memory Study were reported in whole or in part in three different manuscripts since the completion of the study in April 2011, with the most comprehensive reporting contained in Exhibit Q hereto.

31. In addition, in 2016, *Advances in Mind Body Medicine* published a peer-reviewed paper titled, "Effects of a Supplement Containing Apoaequorin on Verbal Learning in Older Adults in the Community," which reported on a subset of results from the Madison Memory Study (the "*Advances* Publication"). A true and correct copy of the *Advances* Publication was produced in discovery as QUI-FTCNY-00003811—QUI-FTCNY-00003818 and is attached hereto as Exhibit T.

32. In or about 2014, Sunsho Pharmaceuticals, Ltd. conducted a human clinical trial concerning Prevagen's efficacy on cognitive functioning and quality of sleep (the "Sunsho Trial"). A true and correct copy of a write-up of the Sunsho Trial was produced in discovery as QUI-FTCNY-0096934—00096953 and is attached hereto as Exhibit U.

The FTC's Investigation and Administrative Process

33. On or about July 22, 2015, the FTC issued a Civil Investigative Demand to Quincy Bioscience Holding Company, Inc. ("CID").

34. Quincy and its counsel participated in meetings with the FTC in connection with the CID.

35. The FTC has not filed a complaint against Defendants pursuant to its administrative process or otherwise pursued an adjudicative proceeding against Defendants, other than this action.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on April 12, 2022.

Mark Underwood